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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/773,503 | 02/06/2004 | Michael E. McClurken | 13045.20USC1 | 6627 |
| 23552 7590 02/01/2008 MERCHANT & GOULD PC P.O. BOX 2903 | | | EXAMINER | |
| | | | PEFFLEY, MICHAEL F | |
| MINNEAPOLIS, MN 55402-0903 | | | ART UNIT | PAPER NUMBER |
| | | | 3739 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | • | MAIL DATE | DELIVERY MODE |
| | | | 02/01/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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| | Application No. | Applicant(s) | - |
| | 10/773,503 | MCCLURKEN, MICHAEL E. | |
| Office Action Summary | Examiner | Art Unit | _ |
| | Michael Peffley | 3739 | |
| The MAILING DATE of this communication Period for Reply | appears on the cover sheet wit | th the correspondence address | |
| A SHORTENED STATUTORY PERIOD FOR RE WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFF after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory per - Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the mearned patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNIC R 1.136(a). In no event, however, may a re- riod will apply and will expire SIX (6) MON atute, cause the application to become AB. | CATION. Poply be timely filed THS from the mailing date of this communication. ANDONED (35 U.S.C. § 133). | |
| Status | | | |
| 1) Responsive to communication(s) filed on 10 | O December 2007. | | |
| | his action is non-final. | | |
| 3) Since this application is in condition for allo | wance except for formal matte | ers, prosecution as to the merits is | |
| closed in accordance with the practice unde | er <i>Ex parte Quayle</i> , 1935 C.D. | . 11, 453 O.G. 213. | |
| Disposition of Claims | • | | |
| 4)⊠ Claim(s) <u>37-65</u> is/are pending in the applica | ation. | | |
| 4a) Of the above claim(s) 52 is/are withdraw | n from consideration. | | |
| 5) Claim(s) is/are allowed. | | | |
| 6)⊠ Claim(s) <u>37-51 and 53-65</u> is/are rejected. | | | |
| 7) Claim(s) is/are objected to. | | | |
| 8) Claim(s) are subject to restriction and | d/or election requirement. | | |
| Application Papers | | | |
| 9)☐ The specification is objected to by the Exam | iner. | | |
| 10)⊠ The drawing(s) filed on <u>2/6/04</u> is/are: a)⊠ a | accepted or b) objected to b | by the Examiner. | |
| Applicant may not request that any objection to t | the drawing(s) be held in abeyand | ce. See 37 CFR 1.85(a). | |
| Replacement drawing sheet(s) including the corr | _ | | |
| 11) The oath or declaration is objected to by the | Examiner. Note the attached | Office Action or form PTO-152. | |
| Priority under 35 U.S.C. § 119 | | | |
| 12) ☐ Acknowledgment is made of a claim for fore a) ☐ All b) ☐ Some * c) ☐ None of: | ign priority under 35 U.S.C. § | 119(a)-(d) or (f). | |
| 1. Certified copies of the priority docume | ents have been received. | | |
| 2. Certified copies of the priority docume | ents have been received in Ap | pplication No | |
| Copies of the certified copies of the p | riority documents have been (| received in this National Stage | |
| application from the International Bur | , | | |
| * See the attached detailed Office action for a l | list of the certified copies not r | received. | |
| | | | |
| AMaska-a-4/a) | | | |
| Attachment(s) Notice of References Cited (PTO-892) | 4) 🖂 Intensions St | ummary (PTO-413) | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s) | /Mail Date : | |
| B) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 5) Notice of Ini 6) Other: | formal Patent Application | |
| | | | |

U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06) Applicant's arguments received December 10, 2007, have been fully considered by the examiner. In particular, applicant's Terminal Disclaimer filed with the response is acceptable and has obviated the double patenting rejections. Also of note, applicant has not provided an accurate copy of claims 63-65 in the December 10, 2007 response. It is noted that the December 15, 2006 amendment by applicant had rewritten claims 63-65 in independent form. The applicant did not attempt to amend the claims in the instant response, and the examiner's rejections and arguments are based on claims 63-65 as presented in the December 15, 2006 communication. The following is a complete response to the December 10, 2007 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 37-51 and 53-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Eggers et al (6,032,674).

Eggers et al disclose a probe that includes an end-effector (i.e. distal end) that may simultaneously provide RF energy via one or more electrodes (270) and fluid (2783 to tissue (see Figure 18). Eggers et al also disclose a dimensional change sensor (310) which is an ultrasound sensor that detects a change in the thickness of tissue as it is being ablated. The sensor is used to control the output of RF energy and alerts the user of changing tissue thickness to prevent creating too deep a channel in tissue (col. 23, lines 50-63). The examiner maintains the device is inherently a "shrinkage sensor" since the channel created by the device is creating a shrinking tissue area (i.e. channel)

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that is being detected by the sensor, and the sensor provides feedback regarding the shrinking of the tissue (i.e. the depth of the channel).

Eggers et al disclose various arrangements for the electrodes, and the device may be operated in either a monopolar or a bipolar manner. Eggers et al also provide for multiple fluid lumens (figure 2a).

Claim Rejections - 35 USC § 103

Claims 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bommannan et al (6,775,575) in view of the teaching of Mulier et al (6,096,037).

The Bommannan et al device comprises an end effector (i.e. forceps jaws) that includes electrodes for treating tissue (see Abstract). Bommannan et al further disclose providing the jaws with sensors (250) for sensing the dimensional change of tissue (e.g. tissue thickness) and controlling the delivery of energy (see col. 5, line 64 through col. 6, line 34). The only feature not expressly taught by Bommannan et al is the provision of a fluid outlet to provide fluid during treatment.

Mulier et al disclose an analogous device for clamping and treating electrodes, and specifically teach that providing an electrolytic solution from fluid outlets in the jaws will enhance the delivery of energy to tissue.

To have provided the Bommannan et al device with a fluid source and fluid outlet to provide fluid to tissue to enhance the delivery of RF energy to tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Mulier et al.

Response to Arguments

Applicant's arguments filed December 10, 2007 have been fully considered but they are not persuasive.

Regarding the 35 USC 102 rejection, applicant contends that the Eggers et al device does not provide a sensor monitors dimensional change. Applicant asserts that the Eggers et al ultrasound sensor monitors delay time, and translates that data to a dimensional change. The examiner agrees with applicant's general description of the Eggers et al function, but fails to see why this is not a sensor that measures dimensional change. There is nothing in the claim language that limits the means by which the dimensional change is measures. Whether by micrometer, impedance, visually or any other means, the determination of a tissue dimension by a sensor is deemed to be meet the broad limitation of a "dimensional change sensor". Eggers et al clearly monitor the thickness of the tissue beyond the channel to prevent creating a channel that goes too deep, and therefore clearly monitor the changing dimension of the tissue.

Applicant further asserts that the Eggers et al device does not measure the empty space of the channel. The examiner again agrees with this characterization, but fails to see the point of the argument. The examiner's point in the recited language of the rejection is that the Eggers et al ultrasound sensor could be considered a "shrinkage sensor" since the channel is creating a shrinking tissue area. The examiner maintains this is a valid point. As the channel gets deeper, the tissue distal to the channel continues to shrink, and the ultrasound sensor monitors that shrinking tissue to assure

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the channel does not go completely through the tissue. The "shrinking" of the tissue, which is caused by the creation of the channel, is clearly sensed by the ultrasound sensor of the Eggers et al device.

Regarding the obviousness rejection, applicant readily admits that Bommannan et al disclose a tissue dimension sensor (page 9, second fully paragraph), then states that Bommannan et al do not teach or suggest a sensor as claimed by the applicant. It is noted that claims 63-65, as presented in the amendment of December 15, 2006, merely recite "a dimensional change sensor". There is nothing in the claims that defines or limits the specific type of sensor. The examiner maintains that Bommannan et al clearly disclose a dimensional change sensor (as acknowledged by applicant), and that there is proper motivation to provide a fluid delivery mechanism to the Bommannan et al forceps device in view of the teaching of Mulier et al.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/ Primary Examiner Art Unit 3739

/mp/ January 23, 2008